Accordingly, all of the outstanding rejections under Section 112, directed previously toward the original claim of a method of treating a disease, are no longer applicable. In particular:

-"the specification fails to provide guidance as to how to make or use the claimed composition in a method of therapeutic treatment". The new claim is not directed to a method of therapeutic treatment.

-the examiner questions the method of administration as a key factor in determining inducing of tolerance. As applicant has stated in great detail in the specification (pages 11-19), it is clear that tolerance induction to alpha B-crystallin is fully in line with basic rules of tolerance found with respect to other antigens.

-"exacerbating the condition by administering an antigen peptide". First of all, alpha B-crystallin is not a peptide, and therefore the examiner's position on exacerbation is not applicable. Furthermore, the claim is not directed toward treating a disease condition per se, but is only directed to inducing a tolerance. Thus, any perceived chance of exacerbation of a disease condition is not applicable to the present scope of the claim.

-"duration of the toleragenic effect" - again, applicant has clearly shown in a reduction in T cell response, and this result is all that is presently claimed. Applicant does not claim any particular duration of the reduction.

Applicant has shown that, following the basic rules of antigen tolerance induction, it has surprisingly been able to achieve a tolerized reduction of T cell response to the

self-antigen alpha B-crystallin. The skilled person would be clearly guided by the experimental guidelines, the results shown in the data, and the general principles of antigen tolerance induction, to which alpha B-crystallin has been shown to comply, in order to readily practice the invention. Accordingly, the present claim is acceptable under Section 112, first paragraph.

During the interview, the examiner raised the issue of whether the new claim would satisfy the utility requirement of 35 U.S.C. 101. The claim is directed toward inducing a reduction in the response to T cells specific for alpha B-crystallin. Since an autoimmune response, such as T cell response is unwanted in humans with respect to the body's own alpha B-crystallin, a method which reduces this response is useful for addressing this problem. Applicants have set forth in great detail in the specification, substantial evidence which tends toward a reasonable conclusion that an abnormal, autoimmune reaction to the alpha B-crystallin within the body, is a likely candidate for an underlying cause of multiple sclerosis. It is not necessary at this stage that applicants definitively prove this link, or prove an effective treatment of MS on this basis. Where an applicant discloses a specific biological activity (reduction of T cell response specific to alpha B-crystallin) and *reasonably correlates* that activity to a disease condition (multiple sclerosis) and a potential treatment thereof, then utility is present. See MPEP 2107.01 (August 2001), p. 2100-32.

Although applicants have shown *in vivo* utility for reducing this unwanted T cell response, the parallel to the

acceptance of utility for even *in vitro* testing, is appropriate. In *Cross v. Iizuka*, 224 USPQ 739 (Fed. Cir. 1985), the Court stated that "successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing ... thereby providing an immediate benefit to the public". Likewise, the successful showing of *in vivo* reduction in response to alpha B-crystallin specific T cells, will certainly direct efforts toward furthering a treatment of MS based on the claimed administration step.

Claims 1-4 stand rejected under 35 U.S.C. 102(f). The examiner notes that WO 95/33997 shows three inventors, while the present application shows two. The examiner is invited to review the early papers in the file of the parent application ser. No. 08/975696, in which a correction of inventorship was effected. In those papers, it was demonstrated that the third named inventor, Mr. Ouagmiri, was erroneously named. Accordingly, the inventorship is the same, and the rejection should be withdrawn.

The examiner objects to the specification with respect to the sequence listing submission.

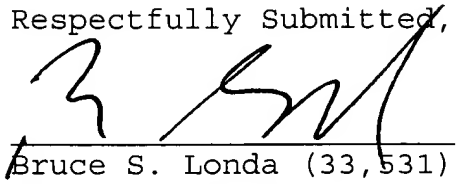
(1) Submitted herewith is a paper copy of the Sequence Listing.

(2) Applicant hereby requests that the CRF in the parent case, ser. no. 08/975,696, be used to prepare the file for the present application.

(3) The paper copy of the Sequence Listing in the present case is identical to the CRF submitted in 08/975,696.

Wherefore, allowance of the pending claim is earnestly solicited.

Respectfully Submitted,



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